1. RECOMMENDATIONS OF THE NDAC (REPRODUCTIVE AND UROLOGY) HELD ON 31.03.2012:-

The NDAC (Reproductive and Urology) deliberated the proposals on 31.03.2012 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
New Drug			
1	**Estradiol 1mg + Drosperinone 2mg**		Committee opined that a phase 3 clinical trial should be conducted on 200 subjects at 4 sites geographically distributed in the country. Protocol for the study should be submitted which will be placed before the committee for evaluation.
2	**Fesoterodine Fumarate 4mg & 8mg**		Committee recommended for giving permission to conduct the proposed clinical trial subject to the following conditions:- i) The study should be conducted on 200 subjects in at least 4 centers geographically distributed in the country. 50 % of the trial sites should be multispecialty hospitals. ii) Urodynamic study should be conducted for all patients. Committee also recommended for giving permission to conduct the proposed bioequivalence study. After completion of the above studies, the reports should be placed before the committee for consideration of approval of the drug in the country.
3	**Ulipristal Acetate 30mg**		Firm had requested for waiver of clinical trial. Committee recommended that a randomised, comparative clinical trial of ulipristal vs levonorgestrel on 200 subjects should be conducted at sites where there is less awareness about emergency contraceptive. Accordingly protocol etc should be submitted to DCG(I) for his consideration and giving approval for the study. However committee recommended for giving permission to conduct the proposed bioequivalence study. After completion of the above studies, the reports should be placed before the committee

			for consideration of approval of the drug in the country.
4	**Dienogest 2mg**		Committee recommended that clinical trial protocol can be approved subject to the following conditions: i) Number of subjects should be at least 200. ii) Sites should be geographically distributed in the country. However before giving final permission by DCG(I) for the clinical trial, subacute toxicity data generated with the source bulk drug should be submitted to DCG(I) for his consideration. Committee also recommended that bioequivalence study should be conducted. Protocol etc. for the same should be submitted to DCG(I) for his consideration.
5	**Fesoterodine**		Experts recommended that clinical trial is required to be conducted on 100 subjects. Accordingly protocol etc should be submitted to DCGI for approval.
6	**Mifepristone**		Recommended for giving permission to conduct the proposed study at the proposed two sites viz. Dr. Suneeta Mittal, AIIMS and Dr. Lakhbir Dhaliwal, PGIMER. Dr. Suneeta Mittal and Dr. Lakhbir Dhaliwal did not participate in the decision making process of this proposal.
7	**Metformin**		Recommended for approval of the study.
8	**Centchroman**		Published data supporting the use of 30mg/day of centchroman have been submitted by the applicant. Committee recommended for approval of the study subject to the following conditions:- i) Patients with oligomenorrhoea/irregular bleeding/ovarian cysts should be excluded from the study. ii) Pelvic ultrasound should be conducted at 3 months and 6 months of follow up. iii) Informed Consent Form as per Appendix V and Investigator Undertaking as per Appendix VII of Schedule Y should be submitted to the office of DCG(I).

9	**Ferrous Sucrose**		Recommended for approval of the study subject to the condition that undertaking from the remaining two investigators should be submitted to DCG(I). Before initiating the study, approval from Ethics Committee should be taken from the same area where the site is located.
Global Clinical Trial			
10	**S-equol(AUS-131)**		Committee opined that use of placebo in patients with BPH for four weeks may not affect the patient's condition. Committee recommended for giving permission to conduct the study subject to the following conditions:- i) The rescue strategy for patients in placebo group should be specified in the protocol. ii) Upper age limit of subjects to be included in the study should be 70 years.
11	**Fesoterodine**		Recommended for approval of the study subject to condition that upper age limit of subjects to be included in the study should be 70 years.
12	**Fesoterodine**		Firm has withdrawn the proposal due to completion of global enrolment.
13	**SH T006581D**		Recommended for approval of the study subject to the following conditions:- i) Subjects aged ≥18 and ≤ 40 years should be included in the study. ii) Undertakings from Investigators should be submitted to DCG(I).

2. RECOMMENDATIONS OF THE NDAC (REPRODUCTIVE & UROLOGY) HELD ON 30.10.2012:-

The NDAC (Reproductive & Urology) deliberated the proposals on 30.10.2012 and recommended the following:

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
1	**Gabapentin**		Committee recommended for approval of the study.
2.	**Nuva Ring**		Committee recommended for approval of the study.
3.	**Ormeloxifene**		Committee recommended for approval of the study.
4.	**Carbetocin**		Phase III clinical trial was permitted at 04 study centres in 240 subjects. However the report of the trial is submitted on 120 subjects from 03 centres. Committee recommended that the firm should complete the trial in 240 subjects and submit the report to the committee for examination.
5.	**DHEA**		Committee recommended for approval of the study.
6.	**Metformin versus insulin**		Committee recommended for approval of the study.
7.	**Tadalafil Tablets**		Deferred for the next meeting.
8.	**Botulinum toxin Type A**		The proposed indication is approved by US-FDA. Committee recommended for giving permission to market 200 unit vials of Botulinum toxin Type A subject to condition that the firm should conduct a multicentric, Phase IV clinical trial on 250 patients within a period of 01 year. The protocol etc of the study should be submitted to the DCG(I) for approval within 02 months of approval of the product.
9.	**Progesterone SR Vaginal Tablets**		Deferred for the next meeting
10.	**Sildenafil citrate Orally Disintegrating Strips**		Deferred for the next meeting
11	**Alfuzocin + Tadalafil**		Deferred for the next meeting

12	**Clotrimazole + lactic acid**		There is no data on safety and efficacy of Clotrimazole alone in spray form. Therefore committee did not consider the proposal of Clotrimazole + lactic acid spray. Hence not recommended for the proposed study.
13	**Dapoxetine HCL + Sildenafil Citrate**		The firm requested to keep their proposal pending as there Medical Director was travelling Abroad. Hence the Proposal was deferred.
14	**Levonorgestrel + Ethinylestradiol**		The firm requested to keep their proposal pending as there Technical Team was travelling Abroad due to preplanned business tour. Hence the Proposal was deferred.
15	**r-FSH**		Firm present the data of the study. After reviewing the data Committee feel that the firm should conduct well authenticated study with proper geographical distribution of study centers across the country and need to generate some more authenticated data as per the approved protocol and submit to the DCG(I) for approval of manufacturing and marketing.
16	**r-FSH**		Deferred for the next meeting
17	**r-HCG**		Deferred for the next meeting
18	**r-FSH**		Deferred for the next meeting
19	**Solifenacin**		Deferred for the next meeting
20	**Fesoterodine**		Deferred for the next meeting

3. RECOMMENDATIONS OF THE (REPRODUCTIVE AND UROLOGY) HELD ON 20.11.2012

The NDAC (Reproductive and Urology) deliberated the proposals on 20.11.2012 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
1	**Isosorbide Mononitrate**		The proposed study is for academic purpose. Committee recommended for giving permission to conduct the study.
2	**Misoprostol & Mifepristone**		The proposed study is for academic purpose. Committee recommended for giving permission to conduct the study.
3	**Probiotic Supplementation**		The proposed study is for academic purpose. Committee recommended for giving permission to conduct the study.
4	**Probiotic**		The proposed study is for academic purpose. Committee recommended for giving permission to conduct the study.
5	**Tadalafil Tablets**		The firm presented various published reports of clinical trials in support of use of Tadalafil 2.5mg/5mg for the proposed claims. The drug is approved for these conditions in other countries including USA. The committee recommended for giving permission to market tadalafil 2.5mg/5mg tablet for ED and ED with BPH. However for tadalafil for BPH, the committee recommended that a 3 arm comparative study of Tadalafil 2.5mg vs tadalafil 5mg vs α blocker in statistically significant number of subjects is required to be conducted. Accordingly, protocol etc should be submitted to DCG(I) for his approval. Results of the study should be submitted to the committee for examination.

6	**Progesterone SR Vaginal Tablets**		The firm initially applied for Progesterone SR vaginal tablet 200mg/400mg. However during presentation the firm also proposed for 300mg strength. The committee recommended that a 4 arm clinical trial with 200mg vs 300mg vs 400mg of the formulation vs conventional vaginal tablet should be conducted. Accordingly revised protocol etc. should be submitted to DCG(I) for his approval. The report of the study should be submitted to the committee for examination.
7	**Sildenafil citrate Orally Disintegrating Strips**		The committee opined that the formulation should be termed as lingually disintegrating strips and recommended for giving permission for the proposed bioequivalence study. Based on the result of the BE study, a comparative clinical trial of the proposed formulation vs. conventional tablets is required to be conducted after getting protocol etc. approved by DCG(I).
8	**Etonogestrel Implant**		Committee recommended that report of the clinical trial conducted with the drug in Indian subjects by ICMR should be submitted for examination.
9	**Fermalac Vaginal Capsules**		The firm submitted the report of the clinical study conducted by them in India. However, committee observed that the study was not conducted as per the protocol approved in terms of microbiological assessments etc. Therefore the committee did not recommend for giving permission to import and market the drug.
10	**Alfuzocin+Tadalafil**		The firm presented various published reports in support of use of this combination. The committee opined that this FDC may be rationale in patients of BPH who has significant lower urinary tract symptoms due to BPH.

			Therefore the committee recommended that a clinical trial of tadalafil 2.5mg + Alfuzocin 10mg vs tadalafil 5mg + Alfuzocin 10mg vs. Alfuzocin 10mg in statistically significant number of patients is required to be conducted. Accordingly, protocol etc. should be submitted to DCG(I) for his approval. Report of the study should be submitted to the committee for examination.
11	**DapoxetineHCL+Sildenafil Citrate**		Committee recommended that the firm should complete the clinical trial and submit the report to the committee for examination. As regards to addition of new sites in the study, the sites should be multispecialty hospitals including Govt. medical colleges/institutions. DCG(I) may approve such additional sites for the study.
12	**Levonorgestrel + Ethinylestradiol**		Phasic pill has no advantage over single dose pill. Further justification for ethinyl estradiol 0.04mg which is a higher dose is not adequate. Therefore committee did not recommend for giving permission to market the product in the country.
13	**Dapoxetin + Tadalafil Tablets**		Committee recommended for giving permission to conduct the proposed clinical trial subject to condition that the sites should be multispecialty hospitals including Govt. medical colleges/institutions. Accordingly details of such sites should be submitted to DCG(I) for his approval.
14	**r-FSH**		The product is already approved and marketed in Korea. Committee recommended that a comparative clinical trial with the test product vs Gonal-f should be conducted on atleast 100 subjects at 4 sites geographically distributed in the country including two Govt. institutions.

			Revised clinical trial protocol alongwith details of sites etc. should be submitted to DCG(I) for his approval. Result of the study should be submitted to the committee for examination.
15	**r-HCG**		Committee recommended that the firm should increase the sample size and number of centers in the study. Details of the revised sites and sample size should be submitted to DCG(I) for his approval.
16	**r-FSH**		Committee recommended for giving permission to conduct the study.
17	**Solifenacin**		Committee recommended for giving permission to conduct the study.
18	**Solifenacin**		Committee recommended for giving permission to conduct the core study as well as the extension study subject to condition that interim report of 10 patients of the study should be submitted to DCG(I) for considering the conduct of the study in pediatrics.

4. RECOMMENDATIONS OF THE (REPRODUCTIVE AND UROLOGY) HELD ON 13.04.2013:-

The NDAC (Reproductive and Urology) deliberated the proposals on 13.04.2013 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
1 to 4	**1 Febuxostat** **2 Pentosan** **3 Dapoxetine** **4 Trospium**		The Committee was apprised that the Parliamentary Standing Committee (PSC) for the Ministry of Health & Family Welfare had presented its 59th report to the Parliament on 08.05.2012 on the functioning of the CDSCO. The report has made various recommendations and observation on various aspects such as approval of New Drugs, Pharmacovigilance, approval of clinical trials etc. The Ministry of Health & Family Welfare has submitted final action taken report on the observation/recommendations contained in the 59th report of the Hon'ble Parliamentary Standing Committee. As per the action taken report, it has been decided by the Ministry that 73 drugs including Fixed Dose Combinations, on approval of which the Hon'ble PSC has made various observations, would be referred to the NDACs for examination and review related to continued marketing of these drugs and updating of their product monographs in light of recent knowledge and regulatory changes overseas. Out of these 73 drugs, 4 drugs are in the category of (Reproductive and Urology) which are given below:- 1 Febuxostat 2 Pentosan 3 Dapoxetine 4 Trospium The NDAC (Reproductive and Urology) discussed the issue and noted that Ministry of Health & Family Welfare has already

			constituted a Committee to formulate policy guidelines and SOPs for a) approval of new drugs, clinical trials, and banning of drugs under the Chairmanship of Dr. Ranjit Roy Chaudhury and b) for approval of the Fixed Dose Combinations under the Chairmanship Dr. C.K. Kokate. Therefore, the Committee opined that these drugs related to continued marketing and updating of the product monograph in the light of recent knowledge and regulatory changes overseas could be examined as per policies, guidelines and SOPs being prepared by the Dr. Ranjit Roy Chaudhury Committee and Dr. C.K. Kokate Committee. However, in the meantime the data/information on safety, efficacy of these five drugs including published data, PMS/PSUR, PSUR data especially on Indian patient required to be prepared in the Form of Dossier. Such data should be prepared from three different sources viz. i) by CDSCO ii) by Pharmacovigilance Programme of India (PvPI) and iii) the firm concerned. The Dossier shall be circulated to all the experts of the NDAC (Reproductive and Urology) for their further review. If needed manufacturer may be requested to make their Presentation before the NDAC on safety and efficacy of the drugs. The NDAC further recommended the following :- CDSCO may collect the following information on all the 4 drugs i) The date of approval of each drug. ii) The date of manufacturing and marketing of each drug by the manufacturer. iii) The mandatory PSUR reports submitted by these companies. iv) Pharmacovigilance data if any from PVPI on these drugs. v) Marketing status of these drugs.

			vi) Global Marketing status of these drugs. vii) Clause, condition and opinion under which permission was granted for these drugs. As soon as the above information is available, a meeting may be called. In the meeting, the recommendations of the other 2 committees may be placed which would be discussed.
5	**Misoprostol**		The Committee recommended for giving permission to conduct the proposed study subject to condition that:- 1. Copper T/ligation should be recommended for the subjects who have completed the family. 2. Only those subjects who offer for suction evacuation should be enrolled in the study.
6	**N-Acetyl Cysteine**		The Committee recommended for giving permission to conduct the proposed study subject to condition that:- 1. Blood glucose level should be estimated at 3 months. 2. Clomiphene citrate should be started with 50mg dose, in case it fails dose should be increased to 100mg.
7	**Sildenafil Citrate topical spray 5 % W/W**		The Committee recommended that the firm should revise the study protocolso that the study is conducted in two parts, first part should be designed to estimate the blood level of Sildenafil, second part of the study should assess the safety and efficacy of the new formulation as compared to the conventional tablet. The study should be conducted at hospitals/institutions having institutional Ethics Committee and emergency facilitation under the supervision of urologists. Accordingly protocol etc. should be submitted for examination of the committee. The methodology of application of topical spray should be explicit so as to reduce the inter-

			subject variability.
8	**Progesterone Vaginal Spray 12.5% w/v**		The committee observed that the proposed formulation is liquid formulation with a new applicator and not a spray. Hence the name of the formulation should be changed accordingly. Committee recommended for giving permission to conduct the proposed bioequivalence study. However phase III comparative clinical trial of the proposed formulation vis-à-vis progesterone vaginal capsule/tablet already approved is required to be conducted at hospitals/institutions having institutional Ethics Committee and Emergency facility. Accordingly protocol etc should be submitted to the committee for evaluation.
9	**Tadalafil Orally Distinegrating Strips 10/20mg**		The committee recommended for giving permission for bioequivalence study.
10	**Dienogest + Ethinyl estradiol**		The committee recommended to conduct Phase III trial in comparison with the standard therapy of Mala D as a comparator. The study should be conducted in 400 subjects (200 subjects in each arm) with the treatment period of 6 cycles. The study should be conducted in Multispecialty hospitals including government hospitals having emergency facilities and institutional ethics committee. Accordingly the firm should submit the protocol etc. to DCG(I) for approval.
11	**Dutasteride + Naftopidil**		The committee recommended for giving permission to conduct the proposed clinical trial subject to the following conditions: (i) Patients with prostate size more than 30 c.c. should only be included in the study. (ii) The study should be a double blind study. Atleast one site each from Kolkata & Gauhati

			should be included in the study.
12	**Estradiol Valerate + Nomegrestrol Acetate**		The committee recommended to conduct comparative clinical trials with Mala D as a comparator. The study should be conducted in 200 subjects (100 subjects in each arm) with the treatment period of 1 year. The study should be conducted in Multispecialty hospitals including government hospitals having emergency facilities and institutional ethics committee.Accordingly the firm should submit the protocol etc. to DCG(I) for approval.
13	**PF-00695838**		The committee recommended for giving permission to conduct the proposed study. The PIS should be modified as per Indian scenario.
14	**Intraamniotic surfactant**		The Committee recommended for giving permission to conduct the proposed study.
15	**r-FSH**		The committee examined the proposal in detail and recommended to give the marketing authorization of the product with the indication of the innovator product.
16	**Sildenafil Orally Disintegrating Strips**		The committee recommended to give marketing authorization of the product with the condition to conduct a Phase IV study in minimum 400 subjects with in a period of one year.
17	**Dapoxetine mouth dissolving tablet**		The committee recommended for approval of the product for manufacturing and marketing in the country.

5. RECOMMENDATIONS OF THE (REPRODUCTIVE AND UROLOGY) HELD ON 17.09.2013:-

The NDAC (Reproductive and Urology) deliberated the proposals on 17.09.2013 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1	**Cyclofem**		Committee opined that all Fixed Dose Combination injectable preparations containing synthetic Oestrogen and Progesterone were prohibited in the country vide GSR No. 743(E) dated 10.08.1989 most probably due to report of misuse of such preparations for pregnancy detection. In present scenario the chances of such misuse is not there as at present many pregnancy detection kits which are very sensitive and various means for satisfactory contraception are available. ICMR has already conducted the clinical trial with the cyclofem in 1275 subjects who were followed up for 10934 women- months of use. The clinical data has been found satisfactory. Available data shows that Fixed Dose Combination injectable preparations containing synthetic Oestrogen and Progesterone (cyclofem) are not associated with change in Bone Mineral Density. Therefore the committee recommended to consider de-notification of banning of the Fixed Dose Combination injectable preparations containing synthetic Oestrogen and Progesterone by appropriate authority. The committee recommended the grant of permission of clinical trial of Cyclofem and NET-EN subject to the following conditions: 1. The study should be titled as extended phase III clinical trial. 2. The study should be conducted at multispecialty hospitals having emergency facilities and institutional ethics committee registered with CDSCO. 3. Details of such sites along with undertaking by the investigators as per appendix VII of schedule Y should be submitted. 4. Informed consent document as per appendix V of schedule Y should be submitted. 5. Undertaking as per Rule 122DAB

			for compensation and providing medical management as per the Rule in case of injury/death in clinical trial. 6. Denotification of the banning of Cyclofem i.e. Fixed Dose Combination injectable preparations containing synthetic Oestrogen and Progesterone 7. The recommendation may be placed before DTAB for further consideration. (Dr. Sunita Mittal and Dr. Lakbir Dhaliwal did not take part in decision making process due to conflict of interest)
2	**Atosiben**		In protocol it is specifically mentioned that the patients should be followed up to 7 days. However, the firm failed to present the followed up data for 7 days as per protocol. Further the trial was conducted at single centre on 100 patients only. The committee opined that the clinical trial report should include the followed data as per the protocol. Trial should also be conducted in at-least 500 patients at geographically distributed multispecialty hospitals/medical college in which 50 % should be government hospital/medical college clinical trial sites. Accordingly protocol should be submitted to the office of DCG (I) to review and approved.
3	**Mirabegron tablets**		The Firm presented Global clinical studies in which India was also the part of global clinical trial and 114 patients was included from India. The committee noted that drug has low side effects as compare to comparative drug used in trail and it would increase the patient compliance. After deliberation the committee recommended for the approval of drug for import and marketing on the basis of presented clinical study reports subject to the condition that firm should conduct Phase IV clinical trial in at-least 500 patients at multispecialty hospitals/medical college having emergency facilities and registered institutional ethics committee with CDSCO geographically distributed in the country and 50 % of trial sites should be government hospital/medical college. Accordingly protocol should be submitted to the

			committee for review and approval. (Dr. N. K. Mohanty did not take part in decision making process due to conflict of interest)
4	**VSL#3**		The applicant submitted reply in respect of NDAC meeting held on 16/3/2013 and presented before the committee. The committee noted that earlier it was recommended that "As far as project is concerned rational of each constituents of the formulation to be used for the study should be stated and accordingly the formulation be suggested. It is advised by the committee to conduct proof of concept study initially through vaginal route for UTI." After deliberation the committee recommended for the conduct of clinical trial by both routes vaginal and oral as per submitted Clinical Trial protocol.
5	**Ethinylestradiol +Gestodene Tablets 20mcg+75mcg**		The firm requested for the clinical trial wavier, After deliberation the committee recommended the clinical trial waiver and for the approval of drug for manufacture and marketing. FDC of ethinylestradiol 20mcg+Gestodene Tablets 75mcg is already approved. The proposed FDC will have lesser adverse events due to reduction in amount of Ethinylestradiol. However, firm should conduct Phase IV clinical trial in at-least 500 subjects at multispecialty hospitals/medical college having emergency facilities and registered institutional ethics committee with CDSCO geographically distributed in the country and 50 % of trial sites should be government hospital/medical college. Accordingly protocol should be submitted to the committee for review and approval.
6	**Dutasteride+Silodosin Soft gelatine and hard gelatine capsule 0.5mg+4mg/8mg**		After detailed deliberation , committee opined that combi-kit of Dutasteride 0.5 mg+Silodosin is rational. However the firm is required to conduct a 3 arm clinical trial with the proposed combikit vis a vis individual drugs in a significant number of subjects and accordinlgly proptcol etc. sholud be submitted for review.
7			Although, Cyclofem product was earlier approved in US and subsequently it was discontinued from US market by Pfizer in 2004 due to commercial reasons following merger of M/s Pharmica and Upjohn with Pfizer as informed by presenting firm,the product is

	Estradiol Cypionate + Medroxyprogesterone Acetate Injection 0.5mg+4mg/8mg5mg/0.05ml+25mg		presently marketed in countries like Latin America, Hongkong & Indonesia etc. The drug is also listed in WHO model list of essential medicines (18th list April 2013). ICMR has already conducted the clinical trial with the cyclofem in 1275 subjects who were followed up for 10934 women- months of use. The clinical data has been found satisfactory. The use of combined progesterone and estrogen (Cyclofem) has not been found associated with change in BMD. The committee recommended that the product Estradiol Cypionate + Medroxyprogesterone Acetate Injection 0.5mg+4mg/8mg5mg/0.05ml+25mg may be approved for marketing in the country subject to de-notification of banning of drug. The recommendation may be placed before DTAB for further consideration.
8	**Desogestrel +Ethinylestradiol tablet 0.15mg+0.03mg**		The product is already approved as contraceptive pill and firm has proposed for marketing the imported product for additional indication- DUB. It was informed by the firm that the product is not approved in country of origin for the proposed additional indication. Accordingly the committee did not recommend for the proposed additional indication.
9	**Pergoveris**		The committee recommended that a Phase III trial shal be conducted and accordingly protocol etc. shall be submitted
10.	**Estradiol Vaginal Tablets**		After deliberation, committee recommended for grant of permission for conduct of clinical trial as per submitted protocol.

6. RECOMMENDATIONS OF THE (REPRODUCTIVE AND UROLOGY) HELD ON 23.01.2014:-

The NDAC (Reproductive & Urology) deliberated the proposals on 23.01.2014 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1.	**Sildenafil**		The committee recommended for minor change in the proposed protocol. 1.The dosage regimen should be twice daily in place of thrice a day (25mg bid) 2.Both study and control subjects should be recruited at the same period of gestation. 3. New born should be followed up for one month.
2.	**Dapoxetine Hydrochloride**		Firm requested for deferment of the proposal in the next forthcoming NDAC meeting.
	Trospium		Firm requested for deferment of the proposal in the next forthcoming NDAC meeting.
3.	**Pentosan**		Firm requested for deferment of the proposal in the next forthcoming NDAC meeting.
4.	**Febuxostat**		Firm requested for deferment of the proposal in the next forthcoming NDAC meeting.
5.	**Medroxyprogesterone Acetate (MPA) 104mg in 0.65ml suspension**		Medroxyprogesterone Acetate 150mg/ml sterile aqueous suspension USP injection (intra-muscular) is approved by this Directorate in the year 1998. Firm has proposed a new drug delivery system of Medroxyprogesterone Acetate (MPA) 104 mg in 0.65 ml suspension by subcutaneous route. The committee opined that as this particular formulation has approved and marketed for several years in other countries and is also recommended by WHO. The proposed formulation is a reduced dose than intra muscular dose and the delivery system is novel and it is convenient for use when compared to the intra muscular route. Firm has also submitted the published reports on over 16,000 patients. Therefore committee recommended for import and marketing of

			Medroxyprogesterone acetate (MPA) 104mg in 0.65 ml suspension for injection in new delivery system and route of administration (subcutaneous). The committee has recommended for the approval subjected to submission of PSUR every six month to the office of DCG(I).
6.	**Combipack of Ethinylestradiol+levonorgestrel**		FDC of Levonorgestrel 150 mcg and Ethinylestradiol 30 mcg tablet is already approved. The firm is only adding 7 pills of placebo/inert tablets to the approved formulation for patient compliance. Already CDSCO, has approved the combipack of 21 tablets of FDC of Ethinyestradiol IP 0.03 mg + Levonorgestrel IP 0.15 mg and 7 tablets of Ferrous Fumarae IP 75 mg. The committee recommended for manufacture and market of proposed combipack of 21 pills of FDC of Levonorgestrel 150 mcg + Ethinyl estradiol 30 mcg tablet and 7 pills of placebo/inert tablets. The proposed combipack is also approved in US, UK and Europe.
7.	**Etonogestrel+Ethinylestradiol**		Firm requested for deferment of the proposal in the next forthcoming NDAC meeting.
8.	**Denosumab**		The committee opined that prevention of skeletal related events in patients with cancer prostate and advanced malignancies involving bone are treated by urologist also and the urologist has also been participated in clinical trial of the subject drug. Further the committee opined that it can be included on the label as “To be sold on the prescription of the Oncologist/Urologist only”.

7. RECOMMENDATIONS OF THE (REPRODUCTIVE AND UROLOGY) HELD ON 13.06.2014:-

The Committee while evaluating the following proposals, the Committee kept in view three following aspects

1. Risk versus benefit to the patients
2. Innovation *vis-à-vis* existing therapies
3. Unmet need in Indian population.

The NDAC (Reproductive & Urology) deliberated the proposals on 13.06.2014 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1.	**Atosiban Acetate Injection 7.5mg/ml**		The Committee was informed that the committee in its earlier meeting held on 17.9.13 had noted that in protocol it is specifically mentioned that the patients should be followed up to 7 days. However firm have failed to present the follow up data for 7 days. The committee noted that there were 86% patients remained undelivered till the end of their hospital stay (follow-up phase) and 88% women remained undelivered up to 72 hrs including treatment phase (48 hrs). and no reports of AE/SAE are reported. Further there were 15 cases of delivery after 6 hours or more of treatment initiation. Further the trial was conducted at single centre on 100 patients only. The Committee opined that since no follow-up data is available for earlier study. The trial should be conducted in at least 500 patients at geographically distributed multispeciality hospitals/medical college in which 50% of the sites should be government hospitals/medical institutions clinical sites across the country. After detailed deliberation the committee reiterated its earlier recommendation that clinical trial is required to be conducted in at least 500 patients at geographically distributed multispeciality hospitals/medical college in which 50% of the sites should be government hospitals/medical institutions clinical sites across the country. The follow up of patients should be till delivery.

			Further the committee recommended that the follow up data of subjects, enrolled in the study, till delivery is also required to be submitted.
1.	**12-160/13-DC** **Nalfurafine capsule 2.5mg**		While considering the application for Nalfurafine capsule 2.5 mcg it was noted that Nalfurafine injection was refused for marketing authorization by EMA in Dec 2013, It was also noted that then preparation of Nalfurafine was to be available as concentrate solution for infusion into a vein whereas the present application is for capsule formulation. The CHMP while recommending the refusal opined that the benefits of 'Winfuran' did not outweigh its risk and recommended that it be refused marketing authorization. After detailed deliberation the Committee recommended that the firm shall submit data/evidence with respect to favorable risk benefit assessment of capsule formulation before it can be reconsidered for conducting clinical trial for further review by the committee.
2.	**Mirabegron tablet 25/50mg**		The firm did not turn up for presentation. Hence the proposal was deferred.
3.	**Fenticonazole**		After detailed deliberation the Committee recommended for the conduct of the clinical trial as per protocol submitted to this office.
4.	**Dapoxetine**		The Committee was informed that the Parliamentary Standing Committee (PSC) of the Ministry of Health & Family Welfare had presented its 59th report to the Parliament on the functioning of CDSCO. The report has made various recommendations and observations on approval of certain new drugs. Dapoxetine is one of such drug. This Directorate had approved the Dapoxetine 30/60mg (Tablets) for treatment of premature ejaculation (PE) in men 18 to 64

			years of age. As per action taken report, it was decided that the drug would be referred to NDAC for examination and review related to continue marketing of these drugs and updating of their product monographs in light of recent knowledge & regulatory changes overseas. The firm presented the international regulatory status, clinical trial data of phase—III clinical trial in Indian subjects, PSUR, and Indian data *vis-a-vis* international data The firm has presented the results of Phase-III clinical trial conducted in 212 subjects. The firm also presented that they have submitted 5 PSUR reports covering a total period of four years. The estimated patients exposure for the drug was approx. 3,155 patient years and the total number of depoxetine 30mg and 60 mg tablets sold during the 3 years was 8,03,654 and 1,74,040 respectively. The firm also mentioned they have discontinued the marketing of the drug in the country due to commercial reasons. Since the firm has voluntarily stopped marketing of the drug, the DCG(I) office should ask other firm who is selling this drug for presenting the case before the committee.
5.	**Trospium**		. Committee opined that more data regarding safety and efficacy shall be collected and submitted to the committee for approval.
6.	**Febuxostate**		The firm did not turn up for the presentation.
	Pentosan		The firm did not turn up for the presentation.

7.	**polysulfate**		
8.	**Tadalafil orally disintegrating strips 10mg/20 mg**		The committee in previous meeting recommended for conducting the BE study. Accordingly firm has completed the study and presented the BE study report before the committee. The test product was found bioequivalence with the comperator. The committee opined that permission may be granted for manufacturing and marketing in the country for already approved indications.
9.	**Sildenafil effervescent tablet 25 mg**		The committee opined that vaginal sildenafil in thin Endometrium is recommended in various literatures. However, a comparative three arm multicentric clinical study is required to be conducted with oral sildenafil vis a vis effervescent vaginal tablet vis a vis vaginal tablet of sildenafil and accordingly firm should submit the protocol before the committee for further consideration.
10.	**Botox (Botulinm Toxin Type A) 100 U and 50 U vials**		This product was approved on 19.3.2013 with a condition of Phase IV for the treatment of adults with urinary incontinence due to detrusor over activity. Firm presented Phase IV non interventional PMS study data before committee. The committee recommended for Phase-IV trial with the condition that more centres shall be included in geographically distributed sites and their ethics committee shall be registered with DCG(I) office.
11	**Medabon (Combipack of Mifepristone and Misoprostol)**		The proposed protocol is with Mifepristone and misoprostol for the termination of pregnancy at 64-140 days of LMP having the primary objective to collect data for registration of a medical abortion regimen. Specifically, to investigate whether both 24h and 48h intervals between mifepristone and misoprostol give similar expulsion rates, accepting a difference of up to 5% at 24h, to justify the use of both intervals in clinical practice. The study is being

			sponsored by Concept Foundation. An India specific study of similar medication was conducted previously by investigator (Dr. Lakhbir Dhaliwal) the objective was although different, comparing the efficacy of misoprostol alone and mifepristone plus misoprostol in sequential manner. The result of the study demonstrated that the sequential treatment was significantly better. The committee reviewed the data and observed that there was no safety concern when sequential medication was given up to 20 weeks of gestation. Dr. Lakhbir Dhaliwal and Dr. Suneeta Mittal did not participate in the decision making process. The other experts agreed with the protocol and recommended to conduct the trial with condition that the investigator (Dr. Lakhbir Dhaliwal) shall submit the authenticated data of previous trial to DCGI office.
12	**Foligraf**		Committee examined the Phase IV protocol and recommended for the conduct of the study.
13.	**Tioconazole (Misc)**		The proposal was earlier deliberated with NDAC (Antimicrobial). The recommendations of the committee was placed before Gynecologists and they also agreed to the recommendation of NDAC (Antimicrobial) and opined that the Firm may be permitted to conduct Phase III clinical trial for the proposed indication.